

## Group 3

# Nutrition Research Project NTDT421

## Research Project Synopsis Format

<i>This is a synopsis. The body of the protocol must be referenced for the complete study information.</i>			
<b>Study Title: The Effects of Maternal Caffeine Consumption on the Outcome of the Child</b>			
<b>Approximate</b>			
<b>Number of Subjects</b>	100	<b>Duration of Subject Participation</b>	30 months
<b>Number of Study Centers</b>	7	<b>Duration of Study</b>	4 years
<b>Background and Rationale:</b> Caffeine is one of the most commonly consumed substances by individuals of different age groups and geographic locations. Caffeine comes from numerous sources such as tea and coffee, which may be consumed on a daily basis, as well as from energy drinks and sodas. Due to its abundance in drinks, it is not uncommon to see caffeine consumption in pregnant women. Potential adverse outcomes have been noted, however, in relation to maternal caffeine consumption and the health status of the infant. Systematic reviews have highlighted the dose-response relationship between caffeine intake and poorer health outcomes, such as lower birth weight, preterm births, and miscarriages. The activity of the liver enzyme responsible for caffeine metabolism is decreased in pregnant women causing caffeine and its metabolites to cross into the placenta and build up in the brain of the fetus. Caffeine easily crosses the placental barrier into the brain of the fetus and caffeine excretion is delayed due to the immaturity of the fetal liver. Increased levels of caffeine increases the concentrations of adrenaline, dopamine, and serotonin which inhibit the transport of nutrients to the fetus. <sup>2</sup> Until recently, healthcare professionals recommended intake of caffeine to not exceed 300 mg per day, however it has changed to 200 mg per day in light of recent studies. <sup>1,2</sup>  Studies evaluating the relationship of maternal caffeine intake and its effects on the infant's growth have yielded conflicting results. Some studies did not have an adverse effect on infant outcomes when the mother consumed caffeine during pregnancy. <sup>1,2,3</sup> Another study found that mothers who consumed a higher amount of caffeine during pregnancy had a higher chance of having a child who was preterm or small for gestational age (SGA). <sup>4</sup> In previous studies the average and median age of the mothers studied were around 30 years old, but no studies have focused on younger populations. <sup>1,2,5</sup> Most studies have also only focused on caffeine consumption through tea and coffee. <sup>1,2,5</sup> Although high amounts of caffeine are in drinks like coffee and tea it is important to study the effects of other caffeine beverages like sodas and energy drinks. The purpose of this study is to examine the correlation between maternal intakes of caffeine in varied amounts on birth outcomes and to study the long-term anthropometric effects on the infant up to 1 year after birth. We hypothesize that increased caffeine consumption through coffee, tea, sodas, and energy drinks will negatively impact birth outcomes in children born from women aged 15 to 22 years old and that the child's growth will be affected up to one year after birth.			
<b>Objectives:</b> The <u>primary objective</u> is to determine how the amount of caffeine consumed by the mother affects the child's weight, length, and head circumference at birth.  The <u>secondary objective</u> is to determine the effect of the mother's caffeine consumption on the growth of the child at 3 months, 6 months, 9 months, and at one year.			
<b>Design:</b> This study is a prospective, longitudinal, and observational study on women who consume caffeine during their pregnancy and their offspring.			
<b>Methods:</b> <ul style="list-style-type: none"><li>• One-hundred WIC eligible females ages 15 to 22-year-olds will be recruited up until eight weeks gestational. The subjects will be patients of the dietitians that are employees of the seven designated WIC study centers across the U.S.</li></ul>			

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- Participants will be screened to determine that they are non-smokers, will not partake in drug or alcohol use during their pregnancy, and do not have any pre-existing health conditions that could affect their pregnancy (i.e. diabetes, heart disease, high blood pressure). The participants' BMI will also be taken into account to ensure they are at a healthy weight status. Prior to pregnancy women must have a BMI of 18.5 - 25 to participate in the study. The weights for the calculated BMI can be obtained from the most up to date medical records prior to pregnancy.
- Throughout the pregnancy, participants will fill out the caffeine consumption questionnaire-revised (CCQ-R) every two weeks which addresses their overall consumption of caffeinated beverages (i.e. coffee, tea, sodas, energy drinks).<sup>6,7</sup> The questionnaire will be filled out and submitted online. The registered dietitians (RDs) will be responsible for reminding subjects they recruited to fill out questionnaires. Subjects must complete a minimum of 75% of the CCQ-R to be included in the analysis population.
- Based on the data from the CCQ-R, RDs will use ranges of mg of caffeine per day to categorize the participants' intake into 4 groups. (i.e. 0 mg/day-would be classified as none, 1-100 mg/d being low, 101-200 mg/d being moderate and 201+ mg/d being classified as high).
- Infant birth weight, length, and head circumference will be collected from the infant's medical record during the first visit with the RD.
- Infant weight, length, and head circumference will be measured by the patients' designated RD at the 3 months, 6 months, 9 months, and one year of life and will be plotted on the WHO growth chart to monitor normal and abnormal growth. Weight will be measured to the nearest 0.01kg using a digital scale, length will be measured to the nearest 0.1 cm using an infantometer, and head circumference will be measured to the nearest 0.1 cm using a non-elastic tape measure.
- At the conclusion, the RDs from across all seven locations, will compile the data to share it with the researchers. The researchers will determine if there was an effect on the mother's consumption of caffeine on the child's growth.

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#### References

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